REMARKS

Claim 1 has been amended to address the 112 rejection. More particularly, claim 1 has been amended to incorporate the limitations of claim 2, i.e., to specify that the package comprises an ingestible membrane. Claim 2 has been cancelled. No new matter has been added by the foregoing amendments.

Claim 1 also has been amended to better define the claimed invention and distinguish the claimed invention from the prior art, i.e., by specifying that the membrane has selected permeability porosity to fluids at a selected site or sites within a patient's alimentary canal. Support is found on page 11 beginning at line 14 of the specification. It is submitted that claim 1, as amended is patentable over all of the applied art.

Considering first the rejection of claims 1, 2, 4 and 9-12 as being anticipated by Depui et al., claim 2 has been cancelled and the subject matter thereof incorporated into claim 1. Depui et al. has been cited as teaching a tablet or capsule containing an acid susceptible protein pump inhibitor together with at least one prokinetic agent in a capsule or tablet in which the protein pump inhibitor is protected by an enteric coating layer. Thus, Depui et al. employs a layer which is intended to be dissolved. In Depui et al., the enteric coated pharmaceuticals are encased within and protected by the enteric coating, and are unavailable until the enteric coating is dissolved. When that happens, the entire dose of pharmaceuticals is then dumped into the patient. Applicants' claimed invention on the other hand employs a pharmaceutical delivery package including an ingestible membrane having a selected permeability porosity to fluids at a selected site or sites within a patient's alimentary canal. Due to the claimed selected permeability porosity, a contained pharmaceutical could only become available at a selected

HAYES SOLOWAY P.C.
130 W. CUSHING STREET
TUCSON, AZ 85701
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

site or sites in the alimentary canal, and, due to the selected permeability porosity, the pharmaceutical would then be released over time. Thus, Applicants' claim 1, and the several claims dependent thereon cannot be said to be anticipated, or for that matter obvious from Depui et al.

Turning to the rejection of claims 1-3, 8, 9 and 12 as anticipated by Barry et al., As note supra, claim 2 has been cancelled, and the subject matter incorporated into claim 1. While Barry et al. may teach a sustained release tablet, Barry et al. nowhere teaches or suggests including two or more different pharmaceutical ingredients combined in and separated from one another in a single delivery package as required by Applicants' claim 1. Accordingly, claim 1 and the several claims dependent thereon also cannot be said to be anticipated by Barry et al.

Turning to the rejection of claims 1-3 and 12 as obvious from Sturzenegger et al., as noted supra, claim 2 has been cancelled and the subject matter incorporated into claim 1. The Examiner cites Sturzenegger et al. as teaching a sustained release pharmaceutical tablet or the like comprising an edible web having two or more medicaments electrostatically deposited onto the web. Sturzenegger et al. teaches forming "dosage units" and stacking several dosage units to form a tablet or the like. However, Sturzenegger, like Barry et al. and Depui et al., fails to teach a pharamaceutical delivery package having fixed unit dose quantities of two or more different pharmaceutical ingredients combined in and separated from one another by an adjustable membrane having a selected permeability porosity to fluids at a selected site or sites within a patient's alimentary canal as required by claim 1. Accordingly, neither claim 1, nor any of the claims dependent thereon can be said to be obvious from Sturzenegger et al.

HAYES SOLOWAY P.C.
130 W. CUSHING STREET
TUCSON, AZ 85701
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

Turning to the rejection of claims 1-10 and 12 as obvious from Sturzenegger et al. in view of Digenis et al., and the rejection of claims 1-9, 11, and 12 as obvious from Sturzenegger et al. in view of Digenis et al. as noted supra, claim 2 has been cancelled and the subject matter thereof incorporated in claim 1. The deficiencies of Sturzenegger et al. vis-à-vis claim 1 are discussed above. It is not seen that Digenis supplies the missing teachings to Sturzenegger et al. to achieve or render obvious claim 1 or any of the claims dependent thereon. The Examiner cites Digenis as teaching a controlled release capsule comprising three or more distinct compartments, each compartment comprising at least one drug. Even assuming arguendo Digenis is as the Examiner states, no combination of Digenis et al. and Sturzenegger et al. reasonably could be said to achieve or render obvious claim 1 or any of the claims dependent thereon. As noted supra, the primary reference Sturzenegger et al. fails to teach a pharmaceutical delivery package formed in part of an adjustable membrane having a selective permeability porosity to fluids at a selected site or sites within a patient's alimentary canal as required by Applicants' claim 1. Digenis et al. also fails to include this teaching. Accordingly, no combination of Sturzenegger et al. and Digenis et al. reasonably could be said to achieve or render obvious claim 1 or the several claims dependent thereon.

The indicated allowability of claims 13-20 is noted with thanks. New independent claim 21 incorporates the essential limitations of claim 1 and claims 13-20 and is believed to be allowable.

The non-statutory double patenting rejections are noted. Applicants will file Terminal Disclaimers upon indication of the claim are otherwise allowable.

Form PTO-2038 in the amount of $200.00 is enclosed for the added independent claim.

HAYES SOLOWAY P.C.
130 W. CUSHING STREET
TUCSON, AZ 85701
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

Having dealt with all the objections raised by the Examiner, the Application is believed to be in order for allowance. Early and favorable action are respectfully requested.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account Number 08-1391.

Respectfully submitted,

Norman P. Soloway
Attorney for Applicant
Reg. No. 24,315

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 11, 2005, at Tucson, Arizona.

By

NPS/JK:sb

HAYES SOLOWAY P.C.
130 W. CUSHING STREET
TUCSON, AZ 85701
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
MANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567